

Massachusetts
Department Of
Public Health



Demonstrating Compliance with
Massachusetts' Ban on Leaded
Children's Jewelry

Guidance Document

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Bureau of
Environmental Health,
Environmental Toxicology
Program

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Guidance Document

I. Background

The Massachusetts Lead Law (MGL c.111, §§ 189A -199B) bans toys, eating or drinking utensils with a coating of paint, enamel or glaze with a lead content of 600 ppm or greater, but the ban does not apply to lead in metallic form. Thus the Massachusetts Department of Public Health (MDPH) has promulgated a regulation that will take effect on October 17, 2008 that defines and bans children's leaded jewelry under the Hazardous Substance Act (MGL c.94B) due to the presence of dangerous levels of lead found in the composition of children's jewelry. During the past three years samples of children's jewelry collected from vending machines, children's toy sections of retail stores, displays in areas near the front entrance of a store, and jewelry counters in stores across the Commonwealth were analyzed for lead and were found to contain dangerous levels of lead. Although the percent of children's jewelry samples containing lead decreased in 2007 from that found in 2004, more than one in ten samples collected in 2007 had sufficiently high lead levels that present serious health concerns to young children. In all cases, these items present the most serious health concerns if the jewelry item is swallowed, but importantly, some of the items can also present significant health concerns if mouthed by young children, a far more common behavior than swallowing.

Thus, despite numerous voluntary recalls of these products issued by the U.S. Consumer Product Safety Commission (CPSC) over the past few years, children's jewelry sold in Massachusetts continues to be found to contain dangerous levels of lead.

The proposed regulation was presented to the Public Health Council on September 12, 2007. The Council expressed strong support for the proposed amendments and asked that MDPH expand the scope of the regulations relative to documentation of compliance with the proposed regulations. As a result of these recommendations, MDPH added language regarding such documentation to the proposed regulations (105 CMR 650.021).

The final regulations were approved by the Public Health Council on March 12, 2008. At that time, MDPH released a draft guidance document for public comment. This guidance document is intended to clarify and facilitate industry compliance with the regulation. This final guidance document takes into consideration comments received. The regulations will take effect on October 17, 2008.

II. The Regulation

Under 105 CMR 650.000 Hazardous Substance Regulation, children's leaded jewelry means jewelry marketed to or intended for use by children under 14 years of age that contains a concentration of lead that either is more than 600 parts per million (ppm) total lead content as determined by the U.S. Consumer Product Safety Commission's (CPSC) screening test for total lead analysis or similar method subject to the approval of Massachusetts Department of Public Health (MDPH) *or* would expose a child to greater than 15 micrograms (μg) of lead per day over a chronic exposure period as determined by the CPSC's acid extraction test. Children's leaded jewelry is jewelry manufactured, shipped or sold at retail or wholesale, indoors or outdoors, over the internet or through catalogs, and includes but is not limited to jewelry (1) sold in: (a) vending machines, (b) toy stores or (c) toy displays, toy departments or toy sections, or (2) that may use images or otherwise be designed or packaged to be especially attractive to children.

III. Compliance

In order to maintain compliance with this regulation, children's leaded jewelry must be analyzed for lead (Pb is the abbreviation for lead) content using the methodologies referenced in the regulation. A sufficient number of samples from each lot, but no less than 0.5 percent (0.5%) of the total number of items in each lot, must be tested to guarantee compliance with the total lead content and acid extraction standards. A lot is defined as the group of items in a production run for which there is no variation of any kind in any ingredient or component used in their manufacture. It is important to note that Massachusetts requires both a total lead analysis and an acid extraction test (which measures accessible lead).

All children's jewelry items offered for sale on the effective date of this regulation will be required to meet the specified standards. Exemptions will not be made for jewelry that had been in-stock prior to the effective date (i.e. "grandfathering"). Precious metals including karat gold, sterling silver, platinum, palladium, iridium, osmium, ruthenium, and rhodium are exempt from this regulation as they are not expected to contain significant quantities of lead.

Jewelry items and jewelry components that are composed entirely of plastic are exempt from this regulation under the Hazardous Substance Act. MDPH has determined that both total lead content and accessible lead in plastic jewelry are unlikely to exceed the standards specified in this regulation. It is important to note that some children's jewelry, including plastic jewelry, is coated. The Massachusetts Lead Law (MGL c.111, ss. 189A-190B) and the Regulations for Lead Poisoning Prevention and Control (105 CMR: 460.000) ban any type of children's jewelry with a coating ≥ 600 ppm of lead as determined by atomic absorption spectrophotometry. Our enforcement surveillance will include coated children's jewelry.

"Jewelry" includes, but is not limited to:

1. Anklet
2. Arm cuff
3. Bracelet
4. Brooch
5. Chain

6. Crown
7. Cuff link
8. Decorated hair accessories
9. Earring
10. Necklace
11. Pin
12. Ring
13. Body piercing jewelry
14. Any bead, chain, link, pendant, or other component of jewelry items

Each item must be tested intact for total lead content and accessible lead depending on its size. If the intact item meets the definition of a small part as specified by CPSC, it is a hazard to children from choking on, inhaling, or swallowing and it must be tested for both accessible lead and total lead content. A small part is any object that fits completely into a small parts cylinder measuring 2.25 inches long by 1.25 inches wide (test described in Appendix A). If the intact item is a small part, the intact item must not exceed 15 µg/day of accessible lead or 600 ppm total lead content.

Additionally, each component of the item must be tested separately using the acid extraction test and the total lead content analysis. Components of jewelry items are pieces that are made of distinct materials and can be separated easily (such as a pendant on a necklace, the clasp of a necklace, or beads of a bracelet) or without the use of a tool (ASTM F 963-07). If any component of the item exceeds 600 ppm total lead, the entire item is not in compliance with the regulation. If any component exceeds 15 µg/day of accessible lead, the entire item is not in compliance. Components of jewelry items that are physically inaccessible, such as the interior components of a watch, are exempt from these requirements.

When testing either the intact jewelry item or a component of an intact jewelry item for total lead content, the portion analyzed must be representative of the intact jewelry item or component (i.e. each type of distinct material must be included in the analysis).

Any jewelry that is not in compliance with the regulation must be disposed of properly. Disposal of non-compliant jewelry by retailers and other commercial and manufacturing operations are subject to the Massachusetts Department of Environmental Protection's Hazardous Waste Regulations (310 CMR 30.000) which can be found at

<http://www.mass.gov/dep/service/regulations/310cmr30.pdf>

For further information on disposal of non-compliant jewelry, please contact James.Paterson@state.ma.us."

The regulations define children as *under* 14 years of age (i.e. age 13 and younger). The lead standards in the regulations do not apply to jewelry for sale to adolescents and adults 14 years of age and over, so it is important for retailers to distinguish between jewelry intended for these two groups. Therefore, most costume jewelry marketed to and intended for use by adults is not impacted by the regulation. While there is no labeling requirement in the regulations, retailers may find it convenient to label jewelry intended for persons 14 years of age and older by adding a label to the packaging or cardboard backing with an alert such as the following: "This item may contain lead, and is not intended for sale to or use by persons 13 years of age and under."

A. Total Lead Content

MDPH approves the CPSC's method for total lead analysis of jewelry, EPA 3050B, and EPA 3051 as appropriate methods for the determination of total lead content of jewelry items. Alternative methods to these methods for total lead are subject to the approval of MDPH. Entities requiring the approval of an alternate method should apply to MDPH's Bureau of Environmental Health, Environmental Toxicology Program (ETP). ETP, in conjunction with the MDPH Bureau of Laboratory Sciences, Environmental Chemistry Laboratory, will review such proposed methods. The total lead content method used to analyze jewelry items must include the following steps:

1. At least 50 mg of the item must be analyzed and be free of contamination.
2. The item must be cut or ground prior to the analysis to increase dissolution.
3. Digestate must be analyzed using either Flame Atomic Absorption Spectrometry, Graphite Furnace Atomic Absorption Spectrometry, Inductively Coupled Plasma Mass Spectrometry, or Inductively Coupled Plasma Emission Spectrometry.
4. The quantitation limit must be at least 500 ppm.

If the chosen laboratory method does not include any one or more of these steps, the method must be modified to include the required step(s).

Results of the total lead analysis must be 600 ppm or less for a jewelry item to be in compliance with the regulation.

B. Acid Extraction Test

The CPSC acid extraction test for accessible lead content (CPSC Standard Operating Procedure for Determining Lead and Its Availability in Children's Metal Jewelry 2/3/2005) must be used to assess accessible lead. The CPSC acid extraction method must comply with the following:

1. Precautions must be taken to avoid cross-contamination of jewelry items and their components. The item must be free of contamination before testing.
2. The entire item must be submerged in the acid solution. In addition, if there are separate components (i.e. a pendant and chain), these items must be analyzed individually, requiring two or more identical jewelry items (See section II "Compliance" for clarity on component parts). Prepare the samples using a 1:50 ratio of sample weight (grams) to leaching solution volume (milliliters).
3. Leachate must be analyzed using Graphite Furnace Atomic Absorption Spectrometry, Inductively Coupled Plasma Mass Spectrometry, or Inductively Coupled Plasma Emission Spectrometry.
4. The laboratory must be able to achieve a quantitation limit sufficient to detect 1.25 µg lead per extraction phase (because the acid extraction test sums results for each of 1, 2, and 3 hour extraction phases for a total of six hours, each phase in the extraction process must achieve a quantitation limit sufficient to detect 1.25 µg lead per 1, 2, or 3 hour

extraction). Items weighing more than 20 grams may require ICP-MS or adjustment to the method.

Note: The acid extraction test frequently results in a number that needs to be adjusted in order to determine whether a jewelry item is in compliance. First, determine if the weight of the analyzed jewelry item must be factored into the lab result in order to obtain a result that reads microgram (μg) / 6 hours. If so, multiply the laboratory result (μg / gram) by the weight of the jewelry (grams). Second, the 6 hour acid extraction test result must be converted to a “per day” result. In order to do so, the 6 hour acid extraction test result must be multiplied by 4 to obtain a result that reads $\mu\text{g}/\text{day}$. This adjusted figure must result in less than $15\mu\text{g}/\text{day}$ for a jewelry item to be in compliance with the MDPH regulation. See example in Appendix B.

IV. Documentation

Retailers must be able to produce documentation that demonstrates that jewelry items have been tested for total lead content and accessible lead in accordance with the methods specified in this guidance document and meet Massachusetts standards. The required documentation form is shown in the Appendix C. This documentation must be available as long as the corresponding jewelry item is being offered for sale and for one (1) year following the cessation of sale of the item. Documentation is required to be available at each retail location. Required documentation may exist on paper or electronically. For stores with multiple cash registers, documentation of testing compliance does not have to be maintained at every register. MDPH inspectors and consumers requesting documentation may be referred to a central location at the retail site, such as a customer service desk. Documentation may be maintained in a loose-leaf binder, accessible paper file(s), or electronically, such as a website accessible on a computer located at the retail location. Such website may be maintained by the retailer, the supplying distributor, the supplying manufacturer, and/or a trade association. A hard copy of documentation (including print-out of website content, where applicable) must be made available to MDPH inspectors upon request. Consumers must be able to examine but do not have to be provided with free hard copies of documentation. The retailer must obtain documentation of test results from the laboratory used by the distributor or manufacturer if the retailer will not be conducting the testing.

Spot checks conducted by MDPH inspectors will require duplicate samples of the jewelry item and a hard copy of the required documentation form related to the jewelry item. The required documentation form must include (a) type and description of jewelry item being sold by retailer (b) lot number (c) name and contact information of the retailer (d) name and contact information of the distributor (e) name and contact information of the manufacturer (f) name and contact information of the laboratory (g) methodology used for and result of the total lead analysis (h) methodology used for and result of the acid extraction test. A sample of the required documentation form (Appendix C) is provided for retailers.

V. Laboratory Quality Assurance/Quality Control

Manufacturers, distributors, and/or retailers must use a qualified laboratory to conduct the required tests. Qualified laboratories have met the standards and qualifications for analysis of lead of the Massachusetts Department of Environmental Protection under 310 CMR 42.00, New

York State Department of Health Environmental Laboratory Approval Program (ELAP), EPA's National Lead Laboratory Accreditation Program (NLLAP), The American Association of Laboratory Accreditation (AALA), or American Industrial Hygiene Association's (AIHA) Environmental Lead Laboratory Accreditation Program (ELLAP). Additionally, any laboratory that has obtained certification from its applicable state agency, such as the state's public health agency or environmental protection agency, showing proficiency in testing for lead (e.g. Connecticut Department of Public Health's Environmental Lead Certification Program) will be qualified to test for lead in jewelry. Laboratories demonstrating the implementation of ISO/IEC 17025:2005 must be accredited or certified by a recognized accreditation body and are qualified to test for lead in jewelry. A limited listing of resources for identifying approved laboratories is attached in Appendix D.

In addition to the required certifications listed above, the approved laboratory must include the following quality control measures for batches of 20 samples or less:

1. A reagent blank resulting in lead levels less than the reporting limit.
2. A Laboratory Fortified Blank spiked at the calibration curve mid-point or lower resulting in 80 – 120% recovery of lead.
3. A Laboratory Fortified Matrix spiked at the calibration curve mid-point or lower resulting in 80 – 120% recovery of lead.
4. A QC material having a certified value of lead within the calibration curve for the method, and/or an in-house established QC material that has been referenced with a certified material or confirmed with external laboratory assistance. The mean, two standard deviations and three standard deviations above and below the mean should be established on 20 results of the material, run on a minimum of five different days. This QC chart should be instrument specific and updated with each batch of samples run by these methods. The QC material aids in control of method and instrument performance. All trends and results outside of three standard deviations must be investigated, corrected and documented.

Laboratories must report the following information to the manufacturer, distributor and/or retailer:

1. Methodology and type of instrument used to determine lead content (e.g. ICP, GFAAS) with quantitation limit.
2. Methodology and type of instrument used to conduct acid extraction test (e.g. ICP, GFAAS) with quantitation limit.
3. Quality control procedure.
4. Percent total lead (to be compared to 600 ppm or 0.06% standard).
5. Sample weight (g).
6. Acid extraction results over 6 hours in units of ppm (to be converted as in Example 1 to $\mu\text{g/day}$ and compared to $15\mu\text{g/day}$ standard).
7. Massachusetts laboratory certification identification number (if applicable).

VI. Surveillance

The Massachusetts Department of Public Health will conduct random spot checks throughout the state to review documentation as required by this regulation (105 CMR 650.210). Collection of children's jewelry to be subsequently analyzed by MDPH Bureau of Laboratory Science will be conducted on an ongoing basis by MDPH environmental health inspectors. At least two samples of each item will be collected in order to conduct both lead compliance tests at BLS.

VII. Penalties for Non-Compliance

Violators of this regulation are subject to the penalties described in M.G.L. Chapter 94B: Hazardous Substances, sections 4, 5 and 8 and M.G.L. Chapter 93A: Consumer Protection Act. Section 4 describes penalties for the sale of a banned hazardous substance. The penalty for a first offense shall be a fine of not less than one hundred dollars nor more than five hundred dollars, or by imprisonment for not more than ninety days, or both. Second and subsequent offense penalties shall be a fine of not less than six hundred dollars nor more than three thousand dollars, or imprisonment for not more than one year, or both. Section 5 authorizes an embargo whenever MDPH finds or has probable cause to believe that any hazardous substance for sale is a banned hazardous substance. Under the consumer protection act, there is a civil monetary penalty of up to \$5000 per violation.

The Hazardous Substances Act, M.G.L. c.94B, requires the repurchase of banned hazardous substances throughout the supply chain, i.e., the manufacturer must repurchase the items from whom he sold it to, who must in turn repurchase the items from the person to whom they sold the items, and so on, to the consumer. In order to qualify for repurchase, the consumer or anyone else seeking repurchase, must present evidence that the item is a banned hazardous substance as defined by the regulation, i.e., laboratory test results.

Concerns have been raised about the potential for frivolous lawsuits being brought against retailers under c.93A. In its most recent and relevant decision regarding liability under c.93A where no loss to the consumer occurred, the Supreme Judicial Court said the following in Hershenow v. Enerprise Rent-a-Car Co. of Boston, 445 Mass. 790, 801-802 (2006):

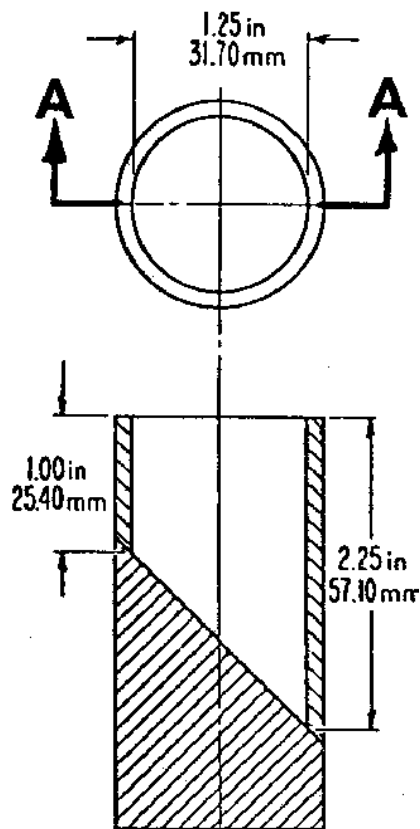
“Every consumer is, of course, entitled to the full protection of law. If any person invades a consumer's legally protected interests, and if that invasion causes the consumer a loss -- whether that loss be economic or non-economic -- the consumer is entitled to redress under our consumer protection statute. A consumer is not, however, entitled to redress under G. L. c. 93A, where no loss has occurred. To permit otherwise is irreconcilable with the express language of G. L. c. 93A, § 9, and our earlier case law.”

The Department of Public Health will act, as appropriate, to prevent the abuse of the Consumer Protection Act, c. 93A, by any potential frivolous suits, consistent with the Supreme Judicial Court's Hershenow decision.

Appendix A: Small Parts Test

1. Place the intact jewelry item, without compressing it, into the small parts cylinder (Figure 1). If the article fits entirely within the cylinder, in any orientation, it must be tested for both total lead content and accessible lead.
2. Any component which can be detached from the article without the use of a tool must be placed into the cylinder, one at a time. If any such components fit entirely within the cylinder, in any orientation and without being compressed, the component must be tested for both total lead content and accessible lead.

Figure 1: Small Parts Cylinder



Appendix B

Example 1. Interpreting Acid Extraction Lab Results

Table 1. Example of Lab results

1 Hour (ppm)	2 Hours (ppm)	3 Hours (ppm)	Total 6 hours (ppm)
2	2	1	5

- Lab result: 5µg Pb / gram jewelry (or 5 ppm) over 6 hours
- Weight of jewelry: 2 grams
- Note: parts per million (ppm) = µg/gram

$$\left(\frac{5\mu\text{g Pb}}{\text{gram jewelry}} \right) / 6 \text{ hours} \times 2 \text{ grams jewelry} = \frac{10\mu\text{g Pb}}{6 \text{ hours}}$$

$$\frac{10\mu\text{g Pb}}{6 \text{ hours}} \times \frac{24 \text{ hours}}{\text{day}} = 40\mu\text{g per day}$$

Finding: This jewelry item or component is not in compliance with the regulation. The adjusted result, 40µg per day, is greater than 15µg per day. This jewelry item could not be sold in Massachusetts.



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Appendix C

DOCUMENTATION FORM FOR CHILDREN' S JEWELRY PURSUANT TO
105 CMR 650.021

105 CMR 650.000 Hazardous Substances Regulation requires that all children's jewelry, as defined in the regulation, must be analyzed for lead content and determined to be in compliance with the regulation before being offered for sale in Massachusetts. Please complete this form to document compliance for each jewelry item and attach the results form from the laboratory.

Name/Description of Jewelry Item (including lot number)	
Retailer (name, address, phone number)	
Distributor (name, address, phone number)	
Manufacturer (name, address, phone number)	
Laboratory (name, address, phone number, type of certification)	
Date of Analysis	
Total Lead Content Result	
Acid Extraction Test Result	
Is the jewelry item in compliance with the regulation?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Name/Title of Individual Certifying Compliance (Printed Name and Signature)	Print name: X_____

Appendix D

Information regarding the certification of the laboratories and a limited listing of approved laboratories can be found at the following websites.

<http://public.dep.state.ma.us/Labcert/Labcert.aspx>

<http://www.wadsworth.org/labcert/elap/lead.html>

<http://www.epa.gov/oppt/lead/pubs/nllaplist.pdf>

<http://www.aiha.org/content/lqap/accred/ellap.htm>

<http://www.a2la.org/dirsearchnew/newsearch.cfm>